JUN 2 5 2003

K023367

510(k) Summary

1. Name/Address of Submitter: NEKS Technologies
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   Canada

2. Contact Person: Daniel Fortin, DMD, MS
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3. Date Summary Prepared: June 16, 2003

4. Device Name: DETECTAR

5. Predicate Devices: Probe®Perio 2000 System (K980749)
   DentalView®PerioView® System (K973492/K982480)
   DIAGNOdent Laser Fluorescence Caries Detection Device (K983658)
   Alpha 4 LS Automated Microtiterplate Processor (K973638)
   Manual periodontal probes [510(k) exempt]

6. Device Description and Intended Use:

   DETECTAR is indicated for use in the detection of subgingival dental calculus. The DETECTAR probe is similar in intended use, size, and shape to a manual periodontal probe. The DETECTAR probe contains an optical fiber that reads the optical signature of dental calculus and converts it into an electrical signal. From that electrical signal a computer analysis identifies the dental calculus. The labeling includes the following statement:

   "CAUTION: The DetecTar™ unit is capable of detecting calculus particles as small as 0.1 mm^2. CAUTION SHALL BE EXERCIZED TO AVOID OVERINSTRUMENTATION IN THE REMOVAL OF VERY SMALL PARTICLES OF CALCULUS. The significance of removal of calculus of 0.1mm^2 is presently unknown. Clinically considered professional judgment shall be applied to the determination of whether detected calculus shall be removed."

7. Brief Description of Non-clinical Testing:

   An *in vitro* evaluation comparing the DETECTAR with a periodontal probe was conducted by three experienced clinicians. A piece of pig gingiva was set on

the root surface of the teeth to simulate the periodontium and conceal the root surface. To complete the model, drops of blood were introduced between the gingiva and the tooth before the clinician performed an evaluation. Seven variables were studied. The DETECTAR significantly outperformed the manual periodontal probe.

8. **Conclusions Drawn: Substantially equivalent to the cited predicate devices.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

NEKS Technologies
C/O Mr. Charles H. Kyper
Kyper & Associates, LLC
103 Nolen Lane
Chapel Hills, North California 27516

Re: K023367
Trade/Device Name: DETECTAR
Regulation Number: 872.4565, 872.1745
Regulation Name: Dental Hand Instrument, Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: EJB, NBL
Dated: June 16, 2003
Received: June 17, 2003

Dear Mr. Kyper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K023367

Device Name: DETECTAR

Indication for Use: DETECTAR is indicated for the detection of subgingival dental calculus

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Concurrence of CDRH Office of Device Evaluation

Prescription Use X OR Over-the-counter Use ____
(per 21 CFR 801.109)

Kevi Hurley for NSD
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K023367